

## **EXECUTIVE SUMMARY**

### **EVALUATION OF THE FOLLOWING THREE CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS STATIONS IN PIERCE COUNTY:**

- **DAVITA, INC. PROPOSING ESTABLISH A TWENTY-ONE STATION DIALYSIS CENTER IN THE CITY OF TACOMA**
- **FRANCISCAN HEALTH SYSTEM PROPOSING TO ESTABLISH AN EIGHT STATION DIALYSIS CENTER IN THE CITY OF LAKEWOOD**
- **FRANCISCAN HEALTH SYSTEM PROPOSING TO ESTABLISH AN EIGHTEEN STATION DIALYSIS CENTER IN SOUTH PIERCE COUNTY**

### **BRIEF PROJECT DESCRIPTIONS**

#### **DaVita Inc.**

This application proposes to establish a dialysis facility in Pierce County. The new facility, to be known as Tacoma Dialysis Center (hereinafter referred to as "TDC"), would have 21 stations and be located within a recently constructed building at 3401 South 19<sup>th</sup> Street in Tacoma. [source: DaVita Application, p3]

The capital expenditure associated with the establishment of the 21-station facility is \$1,392,924. [source: Application, p7] DaVita has already constructed the building that would house the proposed facility.<sup>1</sup> As a result, if this project is approved, DaVita anticipates all 21 stations would become operational within six months of approval. Under this timeline, year 2008 would be the facility's first full calendar year of operation. [source: DaVita Application, p11]

#### **Franciscan Health System**

The two projects submitted on behalf of FHS propose additional dialysis centers in Pierce County--one in the city of Lakewood and one in south Pierce County near the city of Spanaway. Hereinafter, the two projects will be referenced as FHS-Lakewood and FHS-South Pierce.

#### **FHS-Lakewood**

This project proposes an 8-station facility to be located on the St. Clare Hospital campus in the city of Lakewood at 11307 Bridgeport Way Southwest. [source: FHS-Lakewood Application, p9]

The capital expenditure associated with the establishment of the 8-station facility is \$1,102,884. [source: FHS-Lakewood Application, p20] If this project is approved, FHS anticipates commencement of the project in the late summer of year 2007 and all 8 stations would become operational by January 1, 2008. Under this timeline, year 2008 would be the facility's first full calendar year of operation. [source: FHS-Lakewood Application, p11]

#### **FHS-South Pierce**

This project proposes an 18-station facility to be located within leased space in south Pierce County at 14916 Pacific Avenue in Tacoma. [source: FHS-South Pierce Application, pp9 & 12 and Exhibit 6]

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<sup>1</sup> The proposed dialysis center is to be located at the same site as a previously reviewed and denied project. That denial is currently under appeal (Docket #04-06-C-2005CN). DaVita elected to proceed with the construction of that facility even though it is under appeal.

The capital expenditure associated with the establishment of the 18-station facility is \$2,617,804. [source: FHS-South Pierce Application, p20] If this project is approved, FHS anticipates commencement of the project in the late summer of year 2007 and all 18 stations would become operational by January 1, 2008. Under this timeline, year 2008 would be the facility's first full calendar year of operation. [source: FHS-South Pierce Application, p11]

### **APPLICABILITY OF CERTIFICATE OF NEED LAW**

All three projects are subject to Certificate of Need review as the establishment of a new healthcare facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a).

### **CONCLUSIONS**

#### **DaVita, Inc.**

For the reasons stated in this evaluation, the application submitted on behalf of DaVita, Inc. proposing to establish a twenty-one station dialysis center in the city of Tacoma within Pierce County is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is denied.

#### **FHS-Lakewood**

For the reasons stated in this evaluation, the application submitted on behalf of Franciscan Health System proposing to establish an eight station dialysis center in the city of Lakewood within Pierce County is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is denied.

#### **FHS-South Pierce**

For the reasons stated in this evaluation, the application submitted on behalf of Franciscan Health System proposing to establish an eighteen station dialysis center in south Pierce County is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is denied.

**EVALUATION OF THE FOLLOWING THREE CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS STATIONS IN PIERCE COUNTY:**

- **DAVITA, INC. PROPOSING ESTABLISH A TWENTY-ONE STATION DIALYSIS CENTER IN THE CITY OF TACOMA**
- **FRANCISCAN HEALTH SYSTEM PROPOSING TO ESTABLISH AN EIGHT STATION DIALYSIS CENTER IN THE CITY OF LAKEWOOD**
- **FRANCISCAN HEALTH SYSTEM PROPOSING TO ESTABLISH AN EIGHTEEN STATION DIALYSIS CENTER IN SOUTH PIERCE COUNTY**

**PROJECT DESCRIPTIONS**

**DaVita Inc.**

DaVita Inc. (DaVita) is a for-profit corporation that provides dialysis services in over 1,200 outpatient centers located in 41 states and the District of Columbia. DaVita also provides acute inpatient dialysis services in over 850 hospitals throughout the country. [source: DaVita Application, p4]

In Washington State, DaVita owns or operates a total of twelve kidney dialysis facilities in five separate counties--Clark, Franklin, King, Pierce, and Yakima. Below is a listing of the twelve DaVita facilities in Washington. [source: CN historical files]

**Clark**

Vancouver Dialysis Center

**Franklin**

Mid-Columbia Kidney Center

**Yakima**

Mt. Adams Kidney Center  
Union Gap Dialysis Center  
Yakima Dialysis Center

**Pierce**

Lakewood Community Dialysis Center  
Puyallup Community Dialysis Center

**King**

Bellevue Dialysis Center  
Federal Way Community Dialysis Center  
Kent Community Dialysis Center  
Olympic View Dialysis Center  
Westwood Dialysis Center

This application proposes to establish a third dialysis facility in Pierce County. The new facility, to be known as Tacoma Dialysis Center (hereinafter referred to as "TDC"), would have 21 stations and be located within a recently constructed building at 3401 South 19<sup>th</sup> Street in Tacoma. [source: Application, p3]

The capital expenditure associated with the establishment of the 21-station facility is \$1,392,924, of which approximately 55% is related to leasehold improvements at the site; 39% is related to both fixed and moveable equipment; and the remaining 6% is related to architect, engineering, application, consulting, and legal fees. [source: Application, p7]

DaVita has already constructed the building that would house the proposed facility. As a result, if this project is approved, DaVita anticipates all 21 stations would become operational within six months of approval. Under this timeline, year 2008 would be the facility's first full calendar year of operation. [source: Application, p11]

**Franciscan Health System**

Franciscan Health System (FHS) is part of a larger organization known as Catholic Health Initiatives that owns 71 health care facilities in 19 states. Catholic Health Initiatives does not have direct ownership or management of any facilities in Washington State, however, FHS or one of its subsidiaries currently owns or operates a variety of health care facilities in the state. The health care facilities are listed below. [source: Catholic Health Initiatives website; Application, Appendix 1]

**Hospitals**

St. Joseph Medical Center, Tacoma  
St. Clare Hospital, Lakewood  
St. Frances Hospital, Federal Way

**Hospice Agency**

Franciscan Hospice, Tacoma

**Hospice Care Center**

FHS Hospice Care Center, Tacoma

**Skilled Nursing Facility**

Franciscan Care Center, Tacoma

**Dialysis Centers**

Greater Puyallup Dialysis Center, Puyallup  
St. Joseph Dialysis Facility, Tacoma  
Gig Harbor Dialysis Center, Gig Harbor

**Ambulatory Surgery Center**

Gig Harbor Ambulatory Surgery Center, Gig Harbor

The projects submitted on behalf of FHS propose two additional dialysis centers in Pierce County--one in the city of Lakewood and one in south Pierce County near the city of South Pierce. Hereinafter, the two projects will be referenced as FHS-Lakewood and FHS-South Pierce.

**FHS-Lakewood**

This project proposes an 8-station facility to be located on the St. Clare Hospital campus in the city of Lakewood at 11307 Bridgeport Way Southwest. Two of the eight stations would be used for training and home patient support; the remaining six stations would be used for incenter dialysis. All six incenter stations would be equipped with a patient bed, rather than a dialysis chair to accommodate frail patients whose conditions prevent them from tolerating dialysis in the typical upright or chair position. [source: FHS-Lakewood Application, p9]

The capital expenditure associated with the establishment of the 8-station facility is \$1,102,884, of which approximately 48% is related to both fixed and moveable equipment; 33% is related to construction costs; 11% is related to sales tax for both construction and equipment; and the remaining 8% is related to architect, engineering, application, consulting, and legal fees. [source: FHS-Lakewood Application, p20]

If this project is approved, FHS anticipates commencement of the project in the late summer of year 2007 and all 8 stations would become operational by January 1, 2008. Under this timeline, year 2008 would be the facility's first full calendar year of operation. [source: FHS-Lakewood Application, p11]

**FHS-South Pierce**

This project proposes an 18-station facility to be located within leased space in south Pierce County at 14916 Pacific Avenue in Tacoma. It is noted that FHS provided a copy of the draft lease agreement for the site. The draft agreement identifies all costs associated with the lease. If this project is approved, the department would include a term requiring FHS to provide a copy of the executed lease agreement between itself and Tacoma Goodwill Industries (the landlord). [source: FHS-South Pierce Application, pp9 & 12 and Exhibit 6]

The capital expenditure associated with the establishment of the 18-station facility is \$2,617,804<sup>2</sup>, of which approximately 52% is related to construction costs, leasehold improvements, and fixed equipment; 32% is related to moveable equipment; 9% is related to sales tax for both construction and equipment; and the remaining 8% is related to architect, engineering, application, consulting, and legal fees. [source: FHS-South Pierce Application, p20]

If this project is approved, FHS anticipates commencement of the project in the late summer of year 2007 and all 18 stations would become operational by January 1, 2008. Under this timeline, year 2008 would be the facility's first full calendar year of operation. [source: FHS-South Pierce Application, p11]

### **APPLICABILITY OF CERTIFICATE OF NEED LAW**

These three project are subject to Certificate of Need review as the establishment of a new healthcare facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a).

### **CRITERIA EVALUATION**

To obtain Certificate of Need approval, both DaVita, Inc. and FHS must demonstrate compliance for each project with the applicable criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); 246-310-240 (cost containment). Additionally, both applicants must demonstrate compliance for each project with the WAC 246-310-280 (the dialysis station projection methodology and standards) that was in effect prior to January 1, 2007.<sup>3</sup>

### **APPLICATION CHRONOLOGY**

The chronology for each application is provided in Attachment A to this evaluation.

### **COMPARATIVE/SIMULTANEOUS REVIEW AND AFFECTED PERSONS**

The comparative or simultaneous review process promotes the expressed public policy goal of RCW 70.38 that the development or expansion of health care facilities are accomplished in a planned, orderly fashion and without unnecessary duplication. A comparative review allows the department to review similar applications simultaneously to reach a decision that serves the best interests of the community's residents.

In the case of the projects submitted by DaVita and FHS, the department will issue one single evaluation regarding whether all three, any, or none of the projects should be issued a Certificate of Need.

For each application, the other applicant sought and received affected person status under WAC 246-310-010. No other entity sought or received affected person status related to these three projects.

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<sup>2</sup> Within the application, FHS identified its estimated costs to be \$2,867,804 which includes \$250,000 for contingency costs. WAC 246-310-010 does not allow the inclusion of contingency costs; as a result, the estimated capital costs were reduced by \$250,000 to \$2,617,804.

<sup>3</sup> Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), and (6).

## **SOURCE INFORMATION REVIEWED**

- DaVita's Certificate of Need application submitted June 13, 2006
- Franciscan Health System's Lakewood Certificate of Need application submitted June 29, 2006
- Franciscan Health System's South Pierce Certificate of Need application submitted June 29, 2006
- DaVita's supplemental information dated September 1, 2006
- Franciscan Health System's Lakewood supplemental information dated September 6, 2006
- Franciscan Health System's South Pierce supplemental information dated September 6, 2006
- Public comment received during the course of the review or at the December 1, 2006, public hearing
- DaVita's rebuttal comments received December 18, 2006
- Franciscan Health System's rebuttal comments received December 18, 2006
- Years 2001 through 2005 historical kidney dialysis data obtained from the Northwest Renal Network
- September 2006 Northwest Renal Network Quarterly Data
- Licensing and/or survey data provided by the Department of Health's Office of Health Care Survey
- Licensing and/or survey data provided by out of state health care survey programs
- Data obtained from DaVita, Inc.'s webpage ([davita.com](http://davita.com))
- Data obtained from Catholic Health Initiatives' webpage ([catholichealthinit.org](http://catholichealthinit.org))
- Data obtained from Franciscan Health System's webpage ([fhshealth.org](http://fhshealth.org))
- Certificate of Need historical files
- Documents obtained from the record related to Docket #04-06-C-2005CN

## **CONCLUSIONS**

### **DaVita, Inc.**

For the reasons stated in this evaluation, the application submitted on behalf of DaVita, Inc. proposing to establish a twenty-one station dialysis center in the city of Tacoma within Pierce County is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is denied.

### **FHS-Lakewood**

For the reasons stated in this evaluation, the application submitted on behalf of Franciscan Health System proposing to establish an eight station dialysis center in the city of Lakewood within Pierce County is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is denied.

### **FHS-South Pierce**

For the reasons stated in this evaluation, the application submitted on behalf of Franciscan Health System proposing to establish an eighteen station dialysis center in south Pierce County is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need is denied.

**A. Need (WAC 246-310-210)**

Based on the source information reviewed, the department determines that both applicants have not met the need criteria in WAC 246-310-210(1) and (2) and the kidney disease treatment facility methodology and standards in WAC 246-310-280.

- (1) *The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need.*

The Department of Health's Certificate of Need Program uses the methodology outlined in WAC 246-310-280 for projecting numeric need for dialysis stations within a county. Using verified facility utilization information obtained from the Northwest Renal Network (NRN) for the most recent five years, the department projects the need for dialysis stations to serve a service area.<sup>4</sup>

In recent evaluations, the department has evaluated need by examining both linear and non-linear projections of the data. One measure of the accuracy of a regression equation is the determinant of regression, or  $R^2$ .  $R^2$  is a value that describes the relation of actual data to the expected values based on the regression analysis of that data. In general, the closer an equation's  $R^2$  value is to one, the more reliable a regression equation is perceived to be. The department concludes that each value to be estimated should be evaluated using both linear and non-linear regression methods and the regression equation deemed more reliable should be used to predict that data element. In some cases, this will be the non-linear equation; in others, the data may be better described by a linear equation. For those values with small and widely varying numbers, such as the numbers of patients trained for home hemodialysis and peritoneal dialysis, both methods tend to return regression equations with very small  $R^2$  values, indicating that neither method returns a particularly reliable result.

The first step in performing this regression analysis is to determine the service area of the project. WAC 246-310-010 provides the following definition of the ESRD service area:

*"End-stage renal dialysis (ESRD) service areas means each individual county, designated by the department as the smallest geographic area for which kidney dialysis station need projections are calculated, or other service area documented by patient origin."*

DaVita Inc.

Within its application, DaVita asserted that its service area for the proposed TDC was Pierce County, minus the peninsula (Gig Harbor area). During screening the department asked DaVita the following question regarding the proposed service area. [source: Department's July 24, 2006, screening letter, question #1, p2]

*"WAC 246-310-010 provides the definition of ESRD service area as follows:  
'End-stage renal dialysis (ESRD) service areas' means each individual county, designated by the department as the smallest geographic area for which kidney*

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<sup>4</sup> Northwest Renal Network was established in 1978 and is a private, not-for-profit corporation independent of any dialysis company, dialysis unit, or transplant center. It is funded by Centers for Medicare and Medicaid Services, Department of Health and Human Services. Northwest Renal Network collects and analyzes data on patients enrolled in the Medicare ESRD programs, serves as an information resource, and monitors the quality of care given to dialysis and transplant patients in the Pacific Northwest. [source: Northwest Renal Network website]

*dialysis station need projections are calculated, or other service area documented by patient origin’. [emphasis added]*

*Page 1 of the application asserts that the department has defined a Tacoma sub-service area that is currently served by four existing providers: St. Joseph Medical Center in Tacoma, DaVita Lakewood in Lakewood, and the two dialysis centers located in Puyallup. Please provide the zip codes associated with the service area to be served by the proposed facility in Tacoma.”*

DaVita provided the following response to the department’s question above. [source: DaVita September 1, 2006, supplemental information, p2 & Attachment 1]

*“The service area for the DaVita Tacoma Dialysis Center represents all Pierce County zip codes outside of the Gig Harbor area designated by the department as separate from the rest of Pierce County. Within the proposed service area there were 530 in-center hemodialysis patients at year-end 2005. Attachment 1 provides the zip codes along with the city and United States Postal Services comments (e.g. zip codes that are post office box zip codes) for each of the zip codes and the number of year-end 2005 hemodialysis patients. This attachment also provides a map of the service area.”*

In its December 1, 2006, public hearing documents, DaVita revised its service area by providing the following statements. [source: DaVita public hearing documents, p1, & Attachments 1 and 2]

*“The two attached analyses using the Department of Health dialysis station need template project substantial dialysis station need within the Tacoma service area based on growth trends for dialysis patients residing within either a 21-zip code service area or a 26-zip code service area over the 2001 through 2005 time period. [footnote states: Both the 21 and 26 zip code analyses exclude post office zip codes that are applied to service areas under proposed new rules, except post office zip code 98401 has been included. Generally post office zip codes report no patients.] DaVita has recently advocated the 26-zip code service area for a Tacoma-based facility and Program has recently adopted the 21-zip code service area. DaVita expects the Department Health Law Judge will determine the appropriate service area for a Tacoma-based facility in the pending DaVita Tacoma adjudicative proceeding. The 21-zip code service area for Tacoma (Attachment 1) shows an overall station need in 2010 of 67.2 stations rounded up to 68 stations. 50 existing stations for the FHS St. Joseph dialysis unit are subtracted from total station need resulting in a net station need of 18 stations. The 26-zip code service area for Tacoma (Attachment 2) encompasses the FHS St. Joseph and DaVita Lakewood dialysis facilities. The overall station need in 2010 for this service area is 87.6 stations rounded up to 88 stations. 50 existing stations for the FHS St. Joseph facility and 21 existing stations for the DaVita Lakewood dialysis facility are subtracted from total station need resulting in a net station need of 17 stations.”*

Based on the public hearing information quoted above, DaVita has provided a revised response to the departments July 24, 2006, screening question and redefined its service area for TDC using either a 21 or 26-zip code service area. WAC 246-310-090(2)(d) provides the following direction regarding applicant responses to department screening questions:

*“The department shall not accept responses to the department's screening letters later than ten days after the department has given "notification of beginning of review.”*



As noted in the “Application Chronology” portion of this evaluation, as requested in DaVita’s September 1, 2006, screening responses, the department began review of the DaVita and two FHS applications on September 27, 2006. Under that timeline, the latest DaVita could have provided revisions to its proposed service area was 5:00 pm on Monday, October 9, 2006. Therefore, as directed in WAC 246-310-090(2)(d) above, the department cannot accept DaVita’s revised 21 and 26-zip code service area for this review.<sup>5</sup>

Within its application, DaVita applied the numeric methodology for both Pierce county as a whole and its proposed service area of Pierce County minus the peninsula. [source: DaVita Tacoma Application, September 1, 2006, supplemental information, p2]

For Pierce County as a whole, DaVita concluded that the more reliable determinate of regression was linear regression for the number of dialyses and the number of patients when applying the methodology. When applying the methodology to Pierce County minus the peninsula, DaVita concluded that the more reliable determinate of regression was linear for the number of dialyses and non-linear for the number of patients. Once DaVita projected the total number of dialysis stations needed, it appropriately subtracted the existing number of stations within the service area, resulting in a projected net need of additional stations. Table I below shows the results of DaVita’s application of the numeric methodology. [source: DaVita Tacoma Application, pp16-20]

**Table I**  
**Results of DaVita’s Numeric Methodology**

<b>Service Area</b>	<b>2008 Net Station Need</b>	<b>2009 Net Station Need</b>	<b>2010 Net Station Need</b>
Pierce County	22.9	29.6	36.2
Pierce County minus peninsula	25.3	31.4	37.5

As shown in Table I above, the results of DaVita’s numeric methodology projects a net need in 2008 for an additional 23 stations for the entire county and a net need for 25 dialysis stations for the county minus the peninsula. For year 2010, DaVita’s numeric methodology projects an entire county net need of 36 additional stations and a county minus the peninsula net need for 38 stations.

#### FHS-Lakewood and South Pierce

For its two projects in Lakewood and south Pierce County, FHS provided projected patient origin data to support its assertion that its proposed service area is Pierce County as a whole. [source: FHS-Lakewood Application, September 6, 2006, supplemental information, p1; FHS-South Pierce Application, September 6, 2006, supplemental information, p1] As a result, for both projects, FHS applied the numeric methodology to the entire county.

Regarding the determinate FHS concluded that the more reliable determinate of regression was linear regression for the number of dialyses and the number of patients trained for peritoneal dialyses. FHS used non-linear for the number of patients and the number of patients trained for hemodialysis. FHS also appropriately subtracted the existing number of

<sup>5</sup> The statements by DaVita regarding the 21 and 26 zip codes for the Pierce County sub-service area are not entirely accurate. In a previously submitted application for the same location, DaVita identified both the 21 and 26 zip code planning area. The denial of that application is still under appeal. [source: Docket #04-06-C-2005CN, AR 16, 48-50, 469-471, 510, and 512]

dialysis station to derive a net station need. [source: FHS-Lakewood & South Pierce Applications, Exhibit 8, p100]

Table II below shows the results of FHS's application of the numeric methodology. [source: FHS Lakewood Application, Exhibit 8; FHS-South Pierce Application, Exhibit 8]

**Table II**  
**Results of FHS's Numeric Methodology**

<b>Service Area</b>	<b>2008 Net Station Need</b>	<b>2009 Net Station Need</b>	<b>2010 Net Station Need</b>
Pierce County	17	23	29

As shown in Table II above, the results of FHS's numeric methodology show a net need in 2008 for an additional 17 dialysis stations for the entire county which increases to a net need for 29 dialysis stations by the end of year 2010.

#### Department's Application of the Numeric Methodology

As previously stated, the first step in performing this regression analysis is to determine the service area of the project(s). WAC 246-310-010 provides a definition of the ESRD service area to be either an individual county or other service area documented by patient origin. When reviewing applications for new dialysis facilities, the department requires the applicant to identify its proposed service area by zip codes. For new facilities with no patient origin data, typically applicants identify the zip codes it expects to serve. For 37 of 39 counties in Washington State, applicants and the department concur that the ESRD service area is the entire county. For the remaining two counties—King and Pierce—applicants and the department concur that identification of sub-service areas is reasonable. As a result, the department does not typically reject a proposed service area for a new facility unless an applicant's approach is obviously arbitrary or unreasonable.<sup>6</sup>

From 1998 to date, only two entities have submitted applications proposing to establish or add stations in Pierce County—DaVita and FHS. Within their historical applications, both DaVita and FHS have proposed a variety of sub-service areas within Pierce County based on projected patient origin data. [source: CN historical files<sup>7</sup>] As a result, it is inconsistent and unreasonable for either applicant to assert in these current applications that Pierce County as a whole is the service area, as asserted in both FHS applications, or that the entire county, minus the peninsula, is the service area, as asserted in the DaVita application.

Given that all three applications propose new dialysis facilities in Pierce County, historical patient origin data for these facilities are not available. Each applicant is insistent both in the initial applications and screening responses that the service area identified are appropriate. Lacking clear evidence to the contrary, the department will apply the numeric methodology using the service areas submitted by each applicant.

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<sup>6</sup> For example, an arbitrary or unreasonable service area would include zip codes that are not contiguous or deliberately omitted zip codes where an existing facility is located, or zip codes that jump over a county to include portions of another county.

<sup>7</sup> DaVita projects include: Puyallup (04/16/98, 08/04/03, and 10/23/06); Lakewood (03/01/02 and 07/11/03); and Tacoma (08/04/03). FHS projects include: Puyallup (04/27/9 and 12/31/01) Gig Harbor (07/26/02) and Spanaway (08/08/03).

For Pierce County as a whole—the FHS service area—the department determined that the more reliable determinant of regression was linear regression projections for the number of dialyses and patients. For the hemodialysis training projections, both linear and non-linear results were equal. Given that the peritoneal training projections resulted in a negative number regardless of the regression used, the department did not calculate that value. The department’s projections for Pierce County are shown in Table III below. [source: Department’s methodology based on Northwest Renal Network facility utilization data-attached to this document as Appendix B]

**Table III**  
**Department’s Dialysis Station Projections**  
**for Pierce County Based on 2001-2005 Historical Data**

Year	Stations	Existing Capacity	Net Station Need
2008	120	(subtract) 105 <sup>8</sup>	15
2009	125		20
2010	130		25

As shown in Table III above, the department projects a net need for 15 dialysis stations in Pierce County in year 2008, and by the end of year 2010, the dialysis station net need increases to 25.

For the two FHS projects, when comparing the results of Tables II and III above, it is noted that methodology results differ for projection years 2008 through 2010. The department concludes the difference in net need may be attributed to the count of hemodialysis and peritoneal dialysis training stations. WAC 246-310-280 requires calculations of training data obtained from the Northwest Renal Network (NRN) within the numeric methodology. Before year 2004, NRN collected both hemo and peritoneal dialyses data separate from incenter dialyses. Beginning in year 2004, NRN changed its reporting form and now captures the training data within the incenter data. As a result, 2004 and 2005 training data is not available from NRN. To calculate training station need, FHS used NRN data for 2001-2003, and its own facility data for years 2004 and 2005, resulting in five years of historical training data. For its projections, the department used NRN data for 2001-2003, and projected to year 2010 based on three years of historical data. Both the department’s approach and FHS’s approach contain variations from the methodology contained in rules. This is due to the change in data collection by NRN. The department used 2001 through 2003 and includes all data elements verified by NRN. FHS used some data from NRN and some data from its own records. However, FHS does not have the training information from the DaVita facilities in Pierce County that provide training.<sup>9</sup> In summary, using the department’s results shown in Table III for the FHS projects, the department projects a net need for 15 additional stations in Pierce County in year 2008, and by the end of year 2010, the dialysis station net need increases to 25.

For Pierce County, minus the peninsula—DaVita’s proposed service area—the department determined that the more reliable determinate of regression was linear regression projections for the number of dialyses and non linear for the number of patients. For the hemodialysis

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<sup>8</sup> FHS Gig Harbor Dialysis Center-6 stations; FHS Greater Puyallup Dialysis Center-12 stations; DaVita Lakewood Community Dialysis Center-21 stations; DaVita Puyallup Dialysis Center-16 stations; and FHS St. Joseph Medical Center-50 stations.

<sup>9</sup> Training data does not involve large numbers of patients or dialyses, and, therefore does not substantially affect the results of the numeric methodology.

training projections, both linear and non-linear results were equal. Given that the peritoneal training projections resulted in a negative number regardless of the regression used, the department did not calculate that value. The department's projections for DaVita's sub-service areas are shown in Table IV below. [source: Department's methodology based upon Northwest Renal Network facility utilization data-attached to this document as Appendix C]

**Table IV**  
**Department's Dialysis Station Projections for**  
**DaVita's Sub-Service Area Based on 2001-2005 Historical Data**

Year	Stations	Existing Capacity	Net Station Need
2008	113	(subtract) 99 <sup>10</sup>	14
2009	117		18
2010	121		22

As shown in Table IV above, the department projects a net need for 14 additional stations in DaVita's proposed sub-service area in year 2008, and by the end of year 2010, the dialysis station net need increases to 22.

For the DaVita project, when comparing the results of Tables I and IV above, it is noted that methodology results differ for projections years 2008 through 2010. The department concludes the difference is attributed to the historical data used. The need for additional dialysis stations is determined, in part, by applying the numeric portion of the methodology. The numeric methodology projects the total number of stations needed through a three-year future regression analysis of facility and patient origin adjusted data using the previous five years data. Then the number of existing stations or 'existing capacity' is subtracted from the total number of stations needed, resulting in the number of additional stations needed in a county, or the "net need." Full year 2005 data became available on June 13, 2006. Given that DaVita submitted its application on June 13 2006, when preparing this application, years 2000-2004 data was the most recent available five years of data.<sup>11</sup> Based on WAC 246-310-280, the most recent five years of data that should be used is 2001 through 2005. In summary, using the department's results shown in Table IV for the DaVita project, the department projects a net need for 14 additional stations in DaVita's sub-service area in year 2008, and by the end of year 2010, the dialysis station net need increases to 22.

WAC 246-310-280(4) requires that the existing dialysis centers that would stand to lose market share by approval of a project, must be operating at 80% capacity of a 3-patient shift, per non-training station, per year, before additional stations may be added. This standard applies to facilities regardless of whether they are located within or outside an applicant's proposed service area. For this standard, it is critical to review the most current data available, which would reflect the most recent utilization of the dialysis centers. For these three projects, the most current data is the September 2006 quarterly data obtained from the Northwest Renal Network.

There are five dialysis facilities in the county; further based on historical Certificate of Need data, three additional facilities located within south King County provide dialysis services to

<sup>10</sup> FHS Greater Puyallup Dialysis Center-12 stations; DaVita Lakewood Community Dialysis Center-21 stations; DaVita Puyallup Dialysis Center-16 stations; and FHS St. Joseph Medical Center-50 stations.

<sup>11</sup> DaVita did not update its methodology for its Pierce County minus the peninsula service area during the review.

Pierce County patients. [source: Docket #06-01-C-2003CN, AR at 565; and Department of Health Evaluation RE: NKC Auburn Kidney Center CN Application #05-15, pp4-5] The three facilities—Northwest Kidney Centers’ Auburn Kidney Center located in Auburn, DaVita’s Federal Way Dialysis Center located in Federal Way, and DaVita’s Kent Community Dialysis Center located in Kent—would also stand to lose market share if any of the three projects were approved. Table V below summarizes the utilization for all eight facilities—five located within Pierce County and three located within south King County. [source: September 2006, Quarterly Utilization Data]

**Table V**  
**Facility Utilization Data**

Facility Name	# of Incenter Stations	September 2006
<b>PIERCE COUNTY DIALYSIS FACILITIES</b>		
FHS Gig Harbor Dialysis Center	6	77.8%
FHS Greater Puyallup Dialysis Center	12	70.8%
DaVita Lakewood Community Dialysis Center	20	99.2%
DaVita Puyallup Dialysis Center	16	110.4%
FHS St. Joseph Hospital Dialysis Center	50	84.3%
<b>KING COUNTY DIALYSIS FACILITIES</b>		
NKC-Auburn Kidney Center	24	79.2%
DaVita Federal Way Dialysis Center <sup>12</sup>	24	68.1%
DaVita Kent Community Dialysis Center	12	125.0%

#### DaVita Inc.

For its project, DaVita determined that its service area is Pierce County, minus the peninsula. Of the eight facilities identified above, one—Gig Harbor Dialysis Center—is located on the peninsula in Gig Harbor. A review of the most current utilization of the remaining seven facilities reveals that three facilities--FHS’s Greater Puyallup Dialysis Center, NKC’s Auburn Kidney Center, and DaVita’s Federal Way Dialysis Center—are not operating at the 80% standard as required by WAC 246-310-280(4). As a result, this sub-criterion is not met for the DaVita project.

#### FHS-Lakewood and South Pierce

For its projects in Lakewood and south Pierce County, FHS asserts that the service area is Pierce County as a whole. A review of the most current utilization of eight facilities shown in Table V reveals that four facilities—FHS’s Greater Puyallup Dialysis Center, FHS’s Gig Harbor Dialysis Center, NKC’s Auburn Kidney Center, and DaVita’s Federal Way Dialysis Center—are not operating at the 80% standard as required by WAC 246-310-280(4). As a result, this sub-criterion is not met for the two FHS projects.

WAC 246-310-280(5) requires the department to evaluate whether the applicants project that the new dialysis centers would be operating at 80% capacity (748.8 dialyses per non-training station) by the end of their third year of operation. As stated in the project description portion of this evaluation, both DaVita and FHS anticipate completion of their respective

<sup>12</sup> As directed in an HLJ final order, CN #1343 was issued to DaVita on November 30, 2006, approving the addition of 11 stations to Federal Way Dialysis Center, resulting in a 24-station facility. Although the Certificate of Need Program has asked for a reconsideration of this decision, DaVita has a valid CN that increases the facility station capacity and all 24 stations must be counted.

projects by January 2008. Under this timeline, year 2010 would be the third year of operation for all three facilities.

DaVita Inc.

For its project in Tacoma, DaVita projected its utilization as a 21-station facility to be 58% in year 2008; 87% in year 2009; and 103% in year 2010. [source: DaVita Tacoma Application, p16]

FHS-Lakewood

FHS's projections for its 8-station Lakewood facility are 68% in year 2008; 86% in year 2009; and 104% in year 2010. [source: FHS-Lakewood Application, Exhibit 10]

FHS-South Pierce

FHS's projections for its 18-station South Pierce facility are 60% in year 2008; 70% in year 2009; and 80% in year 2010. [source: FHS-South Pierce Application, Exhibit 10]

Given that neither DaVita nor FHS met the standard required under WAC 246-310-280(4), the department concluded dialysis station capacity is currently available within each applicant's proposed service area. As a result, the department concludes that the projections for any of the three projects are not reasonable. This sub-criterion is not met.

- (2) All residents of the service area, including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly are likely to have adequate access to the proposed health service or services.

As previously stated, both applicants currently provide health care services to residents of the service area including low-income, racial and ethnic minorities, handicapped and other underserved groups. To determine whether all residents of the service area would continue to have access to an applicant's proposed services, the department requires applicants to provide a copy of its current or proposed admission policy. The admission policy provides the overall guiding principles of the facility as to the types of patients that are appropriate candidates to use the facility and any assurances regarding access to treatment.

To determine whether low income residents would have access to the proposed services, the department uses the facility's Medicaid eligibility or contracting with Medicaid as the measure to make that determination. To determine whether the elderly would have access or continue to have access to the proposed services, the department uses Medicare certification as the measure to make that determination.

A facility's charity care policy should confirm that all residents of the service area including low-income, racial and ethnic minorities, handicapped and other underserved groups have, or would have, access to healthcare services of the applicant. The policy should also include the process one must use to access charity care at the facility.

DaVita Inc.

To demonstrate compliance with this sub-criterion, DaVita provided a copy of its current admission and indigent care policies that would also be used at the new Tacoma facility. The Admission policy outlines the process/criteria that the TDC will use to admit patients for treatment, and ensures that patients will receive appropriate care at the dialysis center. The Admission Policy also states that any patient with end stage renal disease needing chronic hemodialysis will be accepted for treatment at TDC without regard to race, color,

national origin, sex, age, religion, or disability. [source: DaVita Tacoma Application, Appendix 14]

As previously stated, DaVita currently provides services to Medicare and Medicaid eligible patients at its existing twelve dialysis centers and intends to maintain this status. A review of the Indigent Care Policy provided for TDC identifies the proposed facility's financial resources as including both Medicare and Medicaid revenues.

Additionally, DaVita demonstrated its intent to provide charity care to residents by submitting its charity care policy that outlines the process a patient would use to access this service. Additionally, DaVita included a 'charity care' line item as a deduction from revenue within the pro forma financial documents.

Based on the above information, the department concludes that all residents of the service area would have adequate access to the health services at the proposed Tacoma Dialysis Center. This sub-criterion is met.

#### FHS-Lakewood and South Pierce

To demonstrate compliance with this sub-criterion, FHS provided a copy of its current admission and indigent care policies that would also be used at the two new Pierce County dialysis facilities. The Admission policy outlines the process/criteria that the FHS will use to admit patients for treatment, and ensures that patients will receive appropriate care at the dialysis centers. The Admission Policy also states that any patient with end stage renal disease needing chronic hemodialysis will be accepted for services without regard to race, color, national origin, sex, age, religion, or disability. [source: FHS-Lakewood Application, Exhibit 10; FHS-South Pierce, Exhibit 9]

As previously stated, FHS currently provides services to Medicare and Medicaid eligible patients at its existing healthcare facilities, which includes its three dialysis centers located in Pierce County. A review of the Admission and Charity Care policies confirms FHS's intent to maintain this status and include its proposed Lakewood and South Pierce facilities.

Additionally, FHS demonstrated its intent to provide charity care to residents by submitting its charity care policy that outlines the process a patient would use to access this service. Additionally, for both Lakewood and south Pierce County projects, FHS included Medicare and Medicaid as a revenue source within its pro forma financial data and included a 'charity care' line item as a deduction from revenue within the same documents.

Based on the above information, the department concludes that all residents of the service area would have adequate access to the health services at the proposed at FHS-Lakewood or FHS-South Pierce. This sub-criterion is met for both FHS projects.

## **B. Financial Feasibility (WAC 246-310-220)**

Based on the source information reviewed, the department determines that both applicants have not met the financial feasibility criteria in WAC 246-310-220.

### ***(1) The immediate and long-range capital and operating costs of the project can be met.***

#### **DaVita Inc.**

As stated in the project description portion of this evaluation, if this project is approved, DaVita anticipates commencement immediately and the twenty-one station facility would be operational within six months of approval. Based on this timeline, year 2008 would be TDC's first full year of operation.

For financial review of applications, the department requests data for the first three full years following project completion. Using the financial information provided in the application, Table VI below illustrates the projected revenue, expenses, and net income for years 2008-2010 for TDC. [source: DaVita Tacoma Application, Appendix 9]

**Table VI**  
**Tacoma Dialysis Center**  
**Projected Revenue and Expenses Full Years 2008 - 2010**

	<b>Year 1 (2008)</b>	<b>Year 2 (2009)</b>	<b>Year 3 (2010)</b>
# of stations	21	21	21
# of Treatments	11,433	17,029	20,255
# of Patients	75	111	132
% of Occupancy	58.2%	86.6%	103.0%
Net Patient Revenue	\$ 4,074,232	\$ 6,126,350	\$ 7,356,519
Total Operating Expense	\$ 2,660,519	\$ 3,750,247	\$ 4,471,114
Net Profit or (Loss)*	\$ 1,413,713	\$ 2,376,103	\$ 2,885,405
Net Patient Revenue/Treatment	\$ 356.36	\$ 359.76	\$ 363.20
Total Operating Exp./Treatment	\$ 232.71	\$ 220.23	\$ 220.74
Net Profit per Treatment	\$ 123.65	\$ 139.53	\$ 142.45

\*Includes deductions for charity care and bad debt

As shown in Table VI above, at the projected volumes identified in the application, TDC would be operating at a profit in the first three full years of operation as a 21-station facility. However, given that the department concluded in the need section of this evaluation that dialysis station capacity is currently available within DaVita's identified ESRD service area, the projected number of treatments is likely overstated.

Based on the above information, the department concludes that the project's revenues may be overstated and this sub-criterion is not met.

#### **FHS-Lakewood**

For its eight station Lakewood facility, FHS anticipates commencement immediately upon approval and the facility would be operational by January 1, 2008. Under this timeline, year 2008 would be the new facility's first full year of operation.



Given that the Lakewood facility would be located within FHS's St. Clare Hospital campus and would be operated as a cost center of St. Clare Hospital, FHS provided two sets of financial statements for this project. One set included cost allocations from the hospital, and one set did not include cost allocations. Allocated costs represent the dialysis center's fair share of hospital non-revenue producing expenses (such as administration). Since the dialysis center would be operated as a cost center of St. Clare Hospital, the projections that include cost allocations will be used. Table VII below illustrates the projected revenue, expenses, and net income for years 2008 through 2010 for FHS-Lakewood with cost allocations. [source: FHS-Lakewood Application, Exhibit 10]

**Table VII**  
**FHS-Lakewood Dialysis Project**  
**Projected Revenue and Expenses Full Years 2008 - 2010**

	Year 1 (2008)	Year 2 (2009)	Year 3 (2010)
# of stations	8	8	8
# of Treatments	5,108	6,450	7,791
# of Patients <sup>13</sup>	33	42	50
% of Occupancy	68.2%	86.1%	104.0%
Net Patient Revenue	\$ 2,245,528	\$ 2,797,355	\$ 3,349,182
Total Operating Expense	\$ 2,040,697	\$ 2,324,736	\$ 2,581,785
Net Profit or (Loss)*	\$ 204,831	\$ 472,619	\$ 767,397
Net Patient Revenue/Treatment	\$ 439.61	\$ 433.70	\$ 429.88
Total Operating Exp./Treatment	\$ 399.51	\$ 360.42	\$ 331.38
Net Profit per Treatment	\$ 40.10	\$ 73.27	\$ 98.50

\*Includes deductions for charity care and bad debt

As shown in Table VII above, at the projected volumes identified in the application, FHS's 8-station Lakewood facility would be operating at a profit in the first three full years of operation with cost allocations from the hospital included. The department notes that the facility would also operate at a profit for years 2008 through 2010 without the cost allocations. However, given that the department concluded in the need section of this evaluation that dialysis station capacity is currently available within the FHS-Lakewood identified ESRD service area, the projected number of treatments is likely overstated.

Based on the above information, the department concludes that the project's revenues may be overstated and this sub-criterion is not met.

#### FHS-South Pierce

For its eighteen-station facility to be located in south Pierce County, FHS also anticipates commencement immediately upon approval, and the facility would be operational by January 1, 2008. Under this timeline, year 2008 would be the new facility's first full year of operation.

Given that the south Pierce County facility would also be operated as a cost center of St. Clare Hospital, FHS provided two sets of financial statements for this project. One with cost allocations from the hospital, and one without cost allocations. Since this dialysis center

<sup>13</sup> The number of patients was derived by dividing the projected number of dialyses by 156, then rounding up any fractions to the nearest whole number.

would also be operated as a cost center of St. Clare Hospital, the projections that include cost allocations will be used. Table VIII below illustrates the projected revenue, expenses, and net income for years 2008-2010 for the south Pierce County facility with cost allocations. [source: FHS-South Pierce Application, Exhibit 10]

**Table VIII**  
**FHS-South Pierce Dialysis Project**  
**Projected Revenue and Expenses Full Years 2008 - 2010**

	Year 1 (2008)	Year 2 (2009)	Year 3 (2010)
# of stations	18	18	18
# of Treatments	10,109	11,794	13,478
# of Patients <sup>14</sup>	65	76	87
% of Occupancy	60.0%	70.0%	80.0%
Net Patient Revenue	\$ 4,764,530	\$ 5,558,619	\$ 6,352,707
Total Operating Expense	\$ 3,607,434	\$ 4,084,148	\$ 4,562,591
Net Profit or (Loss)*	\$ 1,157,096	\$ 1,474,471	\$ 1,790,116
Net Patient Revenue/Treatment	\$ 471.32	\$ 471.31	\$ 471.34
Total Operating Exp./Treatment	\$ 356.85	\$ 346.29	\$ 338.52
Net Profit per Treatment	\$ 114.46	\$ 125.02	\$ 132.82

\*Includes deductions for charity care and bad debt

As shown in Table VIII above, at the projected volumes identified in the application, FHS's 18-station south Pierce County facility would be operating at a profit in the first three full years of operation with cost allocations from the hospital included. The facility would also operate at a profit for years 2008 through 2010 without cost allocations. However, given that the department concluded in the need section of this evaluation that dialysis station capacity is currently available within the FHS-South Pierce identified ESRD service area, the projected number of treatments is likely overstated.

Based on the above information, the department concludes that the project's revenues may be overstated and this sub-criterion is not met.

- (2) The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.

DaVita Inc.

The capital expenditure associated with the establishment of the twenty-one station facility is \$1,392,924, and of that amount, 55% is related to leasehold improvements at the site; 39% is related to both fixed and moveable equipment; and the remaining 6% is related to architect, engineering, application, consulting, and legal fees. [source: DaVita-Tacoma Application, p7]

To demonstrate compliance with this sub-criterion, DaVita provided the following statements:

*"...Funding from previously allocated operations funds is the least costly approach. Debt financing for this project will not be required since there is sufficient cash on hand. Furthermore, the method of financing would have no impact on the amount charged for each unit of service."* [source: DaVita-Tacoma Application, p24]

<sup>14</sup> The number of patients was derived by dividing the projected number of dialyses by 156, then rounding up any fractions to the nearest whole number.

The department recognizes that the majority of reimbursements for dialysis services is through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, DaVita also provided the sources of patient revenue shown in the chart shown below. [source: DaVita-Tacoma Application, p25]

Source of Revenue	Percentage of Revenue
Medicare	72%
State (Medicaid)	8%
Insurance/HMO	20%
<b>Total</b>	<b>100%</b>

As shown above, the Medicare and State (Medicaid) entitlements are projected to equal 80% of the revenue at TDC. The department concludes that the majority of revenue is dependent upon entitlement sources that are not cost based reimbursement and are not expected to have an unreasonable impact on charges for services. Further, the cost per dialysis for the proposed project was compared to those of recent kidney dialysis proposals, the average cost per dialysis is reasonable.

However, in the need section of this evaluation, the department concluded that DaVita failed to demonstrate that existing facilities are not available to meet the future need for dialysis services in its proposed service area. Given that the project is not needed at this time, the department concludes that the costs of this project may result in an unreasonable impact on the costs and charges for health services in the community. This sub-criterion is not met.

#### FHS-Lakewood

The capital expenditure associated with the establishment of the 8-station facility is \$1,102,884, of which approximately 48% is related to both fixed and moveable equipment; 33% is related to construction costs; 11% is related to sales tax for both construction and equipment; and the remaining 8% is related to architect, engineering, application, consulting, and legal fees. [source: FHS-Lakewood Application, p20]

To demonstrate compliance with this sub-criterion, FHS provided the following statements related to its Lakewood project:

*“...The majority of end stage renal dialysis reimbursement is through fixed, Medicare per diem rates. This project is not expected to have an impact on the capital costs and operating costs and charges for health services.”* [source: FHS-Lakewood Application, p20]

The department recognizes that the majority of reimbursements for dialysis services is through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, FHS also provided the sources of patient revenue shown in the chart shown below. [source: FHS-Lakewood Application, p21]

Source of Revenue	Percentage of Revenue
Medicare	88.8%
State (Medicaid)	2.5%
Insurance/HMO	8.7%
<b>Total</b>	<b>100.0%</b>

As shown above, the Medicare and State (Medicaid) entitlements are projected to equal more than 90% of the revenue at FHS's new dialysis center in Lakewood. The department concludes that the majority of revenue is dependent upon entitlement sources that are not cost based reimbursement and are not expected to have an unreasonable impact on charges for services. Further, the cost per dialysis for the proposed project was compared to those of recent kidney dialysis proposals, the average cost per dialysis is reasonable.

However, in the need section of this evaluation, the department concluded that FHS failed to demonstrate that existing facilities are not available to meet the future need for dialysis services in its proposed service area. Given that the project is not needed at this time, the department concludes that the costs of this project may result in an unreasonable impact on the costs and charges for health services in the community. This sub-criterion is not met.

#### FHS-South Pierce

The capital expenditure associated with the establishment of the 18-station facility is \$2,617,804, of which approximately 52% is related to construction costs, leasehold improvements, and fixed equipment; 32% is related to moveable equipment; 9% is related to sales tax for both construction and equipment; and the remaining 8% is related to architect, engineering, application, consulting, and legal fees. [source: FHS-South Pierce Application, p20]

To demonstrate compliance with this sub-criterion, FHS provided the following statements related to its south Pierce County project:

*"...The majority of end stage renal dialysis reimbursement is through fixed, Medicare per diem rates. This project is not expected to have an impact on the capital costs and operating costs and charges for health services."* [source: FHS-South Pierce Application, p20]

The department recognizes that the majority of reimbursements for dialysis services is through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, FHS also provided the sources of patient revenue shown in the chart shown below. [source: FHS-South Pierce Application, p21]

Source of Revenue	Percentage of Revenue
Medicare	88.8%
State (Medicaid)	2.5%
Insurance/HMO	8.7%
<b>Total</b>	<b>100.0%</b>

As shown above, the Medicare and State (Medicaid) entitlements are projected to equal more than 90% of the revenue at FHS's new dialysis center in south Pierce County. The department concludes that the majority of revenue is dependent upon entitlement sources that are not cost based reimbursement and are not expected to have an unreasonable impact on charges for services. Further, the cost per dialysis for the proposed project was compared to those of recent kidney dialysis proposals, the average cost per dialysis is reasonable.

However, in the need section of this evaluation, the department concluded that FHS failed to demonstrate that existing facilities are not available to meet the future need for dialysis services in its proposed service area. Given that the project is not needed at this time, the department concludes that the costs of this project may result in an unreasonable impact on the costs and charges for health services in the community. This sub-criterion is not met.

(3) *The project can be appropriately financed.*

DaVita Inc.

As previously stated, the capital expenditure associated with the establishment of the twenty-one station facility is \$1,392,924, of which 55% is related to leasehold improvements at the site; 39% is related to both fixed and moveable equipment; and the remaining 6% is related to architect, engineering, application, consulting, and legal fees. [source: DaVita-Tacoma Application, p7] A review of DaVita's historical financial statements shows the funds necessary to finance the project are available.

Based on the information provided, the department concludes the establishment of TDC would not adversely affect the financial stability of DaVita as a whole. This sub-criterion is met

FHS-Lakewood

The capital expenditure associated with the establishment of the 8-station facility is \$1,102,884, of which approximately 48% is related to both fixed and moveable equipment; 33% is related to construction costs; 11% is related to sales tax for both construction and equipment; and the remaining 8% is related to architect, engineering, application, consulting, and legal fees. [source: FHS-Lakewood Application, p20] A review of FHS's historical financial statements shows the funds necessary to finance the project are available. [source: FHS-Lakewood Application, Appendix 2]

Based on the information provided, the department concludes the establishment of an 8-station facility in Lakewood would not adversely affect the financial stability of FHS as a whole. This sub-criterion is met

FHS-South Pierce

The capital expenditure associated with the establishment of the 18-station facility is \$2,617,804, of which approximately 52% is related to construction costs, leasehold improvements, and fixed equipment; 32% is related to moveable equipment; 9% is related to sales tax for both construction and equipment; and the remaining 8% is related to architect, engineering, application, consulting, and legal fees. [source: FHS-South Pierce Application, p20] A review of FHS's historical financial statements shows the funds necessary to finance the project are available. [source: FHS-South Pierce Application, Appendix 2]

Based on the information provided, the department concludes the establishment of an 18-station facility in south Pierce County would not adversely affect the financial stability of FHS as a whole. This sub-criterion is met

**C. Structure and Process (Quality) of Care (WAC 246-310-230)**

Based on the source information reviewed, the department determines that both applicants have not met the structure and process (quality) of care criteria in WAC 246-310-230.

- (1) A sufficient supply of qualified staff for the project, including both health personnel and management personnel, are available or can be recruited.

DaVita Inc.

To staff its 21-station facility, DaVita proposes to recruit 16.5 FTEs in full year one (2008), which would increase to a total of 26.3 FTEs by the end of year three (2010). A breakdown of the proposed FTEs is shown in Table IX below. [source: DaVita-Tacoma Application, p21]

**Table IX  
Tacoma Dialysis Center Projected FTEs**

<b>Staff/FTEs</b>	<b>2008 Projected</b>	<b>2009 Increase</b>	<b>2010 Increase</b>	<b>Total FTEs</b>
Administrator	1.00	0.00	0.00	1.00
Medical Director	Professional Services Contract			
RN	4.00	1.00	2.00	7.00
Patient Care Techs	7.60	4.40	0.00	12.00
Biomedical Techs	0.50	0.00	0.00	0.50
Re-Use Tech	1.00	0.50	0.50	2.00
Administrative Assistant	0.80	0.20	0.20	1.20
MSW	0.80	0.20	0.20	1.20
Dietitian	0.80	0.40	0.20	1.40
<b>Total FTE's</b>	<b>16.50</b>	<b>6.70</b>	<b>3.10</b>	<b>26.30</b>

As shown in Table IX above, after the initial recruitment of FTEs, DaVita expects a minimal increase in FTEs for TDC through year 2010. DaVita states it expects no difficulty in recruiting staff for TDC because of its competitive wage and benefit package offered to employees. Further, DaVita posts staff openings nationally both internally and external to DaVita. In addition, DaVita states that several employees have already expressed interest in working at its proposed Tacoma facility. [source: DaVita Tacoma Application, p27]

Based on this information, the department concludes that adequate staffing for TDC is available or can be recruited. This sub criterion is met.

FHS-Lakewood

To staff its 8-station facility, FHS proposes to recruit 9.79 FTEs in full year one (2008), which would increase to a total of 11.65 FTEs by the end of year three (2010). A breakdown of the proposed FTEs is shown in Table X on the following page. [source: FHS-Lakewood Application, p22]

**Table X**  
**FHS-Lakewood Dialysis Center Projected FTEs**

<b>Staff/FTEs</b>	<b>2008 Projected</b>	<b>2009 Increase</b>	<b>2010 Increase</b>	<b>Total FTEs</b>
Clinical Nurse Manager	1.00	0.00	0.00	1.00
Medical Director	Professional Services Contract			
RN	2.50	0.43	0.24	3.17
Patient Care Techs	3.74	0.60	0.59	4.93
Administrative Assistant	1.05	0.00	0.00	1.05
MSW	0.78	0.00	0.00	0.78
Dietitian	0.72	0.00	0.00	0.72
<b>Total FTE's</b>	<b>9.79</b>	<b>1.03</b>	<b>0.83</b>	<b>11.65</b>

As shown in Table X above, after the initial recruitment of FTEs, FHS expects a minimal increase in FTEs for its Lakewood facility through year 2010. FHS states it expects no difficulty in recruiting staff for the dialysis center because of the significant presence of FHS in the community. Further, in both years 2005 and 2006, FHS was named in Washington CEO magazine as one of the best employers. FHS states that based on its past history, recruitment and training of staff for the dialysis center would not be difficult. [source: FHS-Lakewood Application, p24]

Based on this information, the department concludes that adequate staffing for the 8-station dialysis center is available or can be recruited. This sub criterion is met.

#### FHS-South Pierce

To staff its 18-station facility, FHS proposes to recruit 16.03 FTEs in full year one (2008), which would increase to a total of 20.32 FTEs by the end of year three (2010). A breakdown of the proposed FTEs is shown in Table XI below. [source: FHS-South Pierce Application, p22]

**Table XI**  
**FHS-South Pierce Dialysis Center Projected FTEs**

<b>Staff/FTEs</b>	<b>2008 Projected</b>	<b>2009 Increase</b>	<b>2010 Increase</b>	<b>Total FTEs</b>
Clinical Nurse Manager	1.00	0.00	0.00	1.00
Medical Director	Professional Services Contract			
RN	3.67	0.62	0.61	4.90
Patient Care Techs	9.16	1.53	1.53	12.22
Administrative Assistant	1.00	0.00	0.00	1.00
MSW	0.60	0.00	0.00	0.60
Dietitian	0.60	0.00	0.00	0.60
<b>Total FTE's</b>	<b>16.03</b>	<b>2.15</b>	<b>2.14</b>	<b>20.32</b>

As shown in Table XI above, after the initial recruitment of FTEs, FHS expects a minimal increase in FTEs for its south Pierce County facility through year 2010. FHS states it expects no difficulty in recruiting staff for the dialysis center because of the significant presence of FHS in the community. Further, in both years 2005 and 2006, FHS was named in Washington CEO magazine as one of the best employers. FHS states that based on its past

history, recruitment and training of staff for the dialysis center would not be difficult. [source: FHS-South Pierce Application, p24]

Based on this information, the department concludes that adequate staffing for the 18-station dialysis center is available or can be recruited. This sub criterion is met.

- (2) The proposed service(s) will have an appropriate relationship, including organizational relationship, to ancillary and support services, and ancillary and support services will be sufficient to support any health services included in the proposed project.

DaVita, Inc.

Documentation provided in the application confirms that DaVita maintains appropriate relationships with ancillary and support services for its existing twelve dialysis centers. For TDC, ancillary and support services, such as social services, nutrition services, pharmacy, patient and staff education, financial counseling, human resources, material management, administration, and technical services would be provided on site. Additional services would be coordinated through DaVita's corporate offices in El Segundo, California and support offices in Tacoma, Washington. [source: Application, p18]

DaVita acknowledges that since this would be a new facility in Pierce County, transfer agreements would have to be established. To further demonstrate compliance with this sub-criterion, DaVita provided examples of draft transfer agreements. [source: DaVita-Tacoma Application, p27 and Appendix 12]

Based on this information, the department concludes that DaVita currently has appropriate relationships with ancillary and support services. If this project is approved, the department would include a term requiring DaVita to provide a copy of its executed transfer agreement with the local hospital in Pierce County. Provided that DaVita would agree to the term, this sub-criterion would be met.

FHS-Lakewood and South Pierce

For both projects--8-stations in Lakewood and 18 stations in south Pierce County--St. Clare Hospital will provide monthly social services and dietary support for all patients. Additionally, typical ancillary and support services used by a dialysis program, such as pharmacy, laboratory, radiology, and blood administration will be available from either St. Clare Hospital in Lakewood or St. Joseph Hospital in Tacoma. Since both facilities would be associated with FHS, formal transfer agreements are not necessary, rather, St. Clare or St. Joseph would be the facility of choice for any patients requiring hospital transfer. [source: FHS-Lakewood Application, p24; FHS-South Pierce Application, p24]

Based on this information, the department concludes that FHS currently has appropriate relationships with ancillary and support services. This sub-criterion is met for both FHS projects.

- (3) There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs.

DaVita, Inc.

As stated earlier, DaVita, Inc. is a provider of dialysis services in over 1,200 centers in 41 states and the District of Columbia. [source: DaVita Tacoma Application, p4; and DaVita



Webpage] Currently in Washington State, DaVita owns and operates twelve kidney dialysis treatment centers. As part of its review, the department must conclude that the proposed services would be provided in a manner that ensures safe and adequate care to the public<sup>15</sup>. To accomplish this task, the department requested quality of care compliance history from the state licensing and/or surveying entities responsible for the out-of-state facilities where DaVita, Inc. or any subsidiaries of the parent company has health care facilities. Besides Washington State, the applicant identified 37 states (including the District of Columbia) that are currently providing patient services. In March 2005, the department surveyed the 37 entities and received responses from 30 states and the District of Columbia<sup>16</sup>. Additionally, only Arizona and Iowa had licensing or survey information available via the internet. Therefore, of the 37 states, the department obtained quality of care history for 32 or 86%, plus the District of Columbia. The compliance history of the remaining states is unknown<sup>17</sup>

For the out-of-state facilities, in all states, with the exception of one facility in Georgia, two in New Jersey, ten in New York, the compliance surveys demonstrated either no enforcement actions or minor non-compliance issues that were acceptable by the states and plans of correction were submitted and implemented.

In Georgia, the East Georgia Dialysis Center was fined \$25,000 for non compliance issues related to continuous quality improvement and long term care plans. In New Jersey, Atlantic City Dialysis Center was fined \$5,000 for non-compliance concerning patient services, medical records and policy and procedure discrepancies. Finally, New York had nine facilities with condition level non-compliance issues that were corrected and implemented and the closure of New York Dialysis Center due to condition level non-compliance.

The department concludes that considering the 665 facilities owned/managed by DaVita, only 13 out-of-state facilities listed above demonstrated substantial non-compliance issues, which equates to less than 2%. Therefore, the department concludes the out-of-state compliance surveys are acceptable.

For Washington State, in the most recent 10 years (since January 1996), the Department of Health's Office of Health Care Survey (OHCS) has completed more than 37 compliance surveys for the DaVita facilities in operation.<sup>18</sup> Of the compliance surveys completed, all revealed minor non-compliance issues related to the care and management at the DaVita facilities. These non-compliance issues were typical of a dialysis facility and DaVita submitted and implemented acceptable plans of correction. [source: facility ownership and survey data provided by the Office of Health Care Survey]

Catherine Richardson, MD has agreed to provide medical director services at the proposed dialysis center. DaVita provided a copy of the draft medical director agreement between itself and Dr. Richardson. The agreement outlines the roles and responsibilities of both entities and identifies the annual compensation for the medical director responsibilities.<sup>19</sup> A review of Dr. Richardson's compliance history with the Department of Health's Medical

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<sup>15</sup> WAC 246-310-230(5)

<sup>16</sup> Alabama, California, Colorado, Connecticut, DC, Georgia, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Jersey, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Texas, Virginia, Wisconsin and West Virginia

<sup>17</sup> Delaware, Florida, Illinois, Nevada and Utah.

<sup>18</sup> DaVita's Vancouver Dialysis Center is not yet operational.

<sup>19</sup> The compensation is identified in the pro forma financials provided in the applications at \$35,000 annually.

Quality Assurance Commission reveals no recorded sanctions. [source: Medical Quality Assurance Commission compliance data]

Based on DaVita's compliance history and the compliance history of the proposed medical director, the department concludes that there is reasonable assurance that the TDC would operate in conformance with state and federal regulations. If this project is approved, the department would include a term requiring DaVita to provide a copy of the executed medical director agreement with Catherine Richardson, MD. Provided that DaVita would agree to the term, this sub-criterion would be met.

#### FHS-Lakewood and South Pierce

As stated earlier, FHS is part of a larger organization known as Catholic Health Initiatives that owns 71 health care facilities in 19 states. Catholic Health Initiatives does not have direct ownership or management of any facilities in Washington State, however, FHS or one of its subsidiaries currently owns or operates a variety of health care facilities in the state. [source: Catholic Health Initiatives website; FHS Lakewood and South Pierce Applications, p4]

In Washington State, FHS owns or operates three hospitals, one hospice agency, one hospice care center, one skilled nursing facility, one ambulatory surgery center, and three dialysis centers. [source: FHS Lakewood and South Pierce Applications, p4] As part of its review, the department must conclude that the proposed services would be provided in a manner that ensures safe and adequate care to the public. The Department of Health's Office of Health Care Survey (OHCS) is the licensing and surveying entity for all of the FHS facilities, except the skilled nursing facility. In the most recent 10 years (since January 1996), OHCS has completed more than 30 compliance surveys for the FHS facilities in operation. Of the compliance surveys completed, all revealed minor non-compliance issues related to the care and management at the FHS facilities. These non-compliance issues were typical of the respective healthcare facility and FHS submitted and implemented acceptable plans of correction. [source: facility ownership and survey data provided by the Office of Health Care Survey]

The Department of Social and Health Services is the licensing and surveying entity for the skilled nursing facility owned and operated by FHS. A review of the facility's historical survey data from the Centers of Medicare and Medicaid services (CMS) "Nursing Home Compare" website revealed minor non-compliance issues related to the care and management at the nursing home. These non-compliance issues were typical of the type of facility and when compared to the state and national averages, the FHS nursing home generally fared better than those averages. [source: CMS "Nursing Home Compare" website, accessed at <http://www.medicare.gov/NHCompare>]

David Dempster, MD has agreed to provide medical director services at both new FHS Pierce County dialysis centers. FHS provided a copy of the draft medical director agreement that would be used at the dialysis centers. [source: FHS-Lakewood Application, p6 and Exhibit 2; FHS-South Pierce Application, p6 and Exhibit 2] Both draft agreements outline the roles and responsibilities of both entities, but does not identify the annual compensation for the medical director responsibilities.<sup>20</sup> A review of Dr. Dempster's compliance history with the Department of Health's Medical Quality Assurance Commission reveals no recorded sanctions. [source: Medical Quality Assurance Commission compliance data]

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<sup>20</sup> The compensation is identified in the pro forma financials provided in the application.

Based on FHS's compliance history and the compliance history of the proposed medical director, the department concludes that there is reasonable assurance that the both FHS-Lakewood and FHS-South Pierce would operate in conformance with state and federal regulations.

If the either of the two FHS projects is approved, the department would include a term requiring FHS to provide a copy of the executed medical director agreement with David Dempster, MD. Provided that FHS would agree to the term, this sub-criterion would be met.

- (4) *The proposed project will promote continuity in the provision of health care, not result in an unwarranted fragmentation of services, and have an appropriate relationship to the service area's existing health care system.*

DaVita, Inc

In response to this criterion, DaVita provided a summary of its quality and continuity of care indicators used in its quality improvement program. The quality of care program incorporates all areas of the dialysis program, and monitors and evaluates all activities related to clinical outcomes, operations management, and process flow. Further, continuing education for both employees and patients are integral factors in the quality of care program. DaVita also provided examples of its quality index data and its physician, community, and patient services education offered through its quality of care program. [source: DaVita Tacoma Application, p27, Appendices 18 & 19]

The department also considered DaVita's history of providing care to residents in Washington State. The department concludes that the applicant has been providing dialysis services to the residents of Washington State for several years and has been appropriately participating in relationships with community facilities to provide a variety of medical services. Nothing in the materials reviewed by staff suggests that approval of this project would change these relationships. [source: CN historical files]

Additionally, the department used the most recent utilization data—September 2006--obtained from the Northwest Renal Network to assist in its evaluation of this sub-criterion. According to that data, of the four existing dialysis centers currently operating in DaVita identified ESRD service area, one—FHS Greater Puyallup Dialysis Center—is operating below the 80% utilization standard required before additional stations may be added. Based on this information, the department must reasonably conclude that FHS Greater Puyallup Dialysis Center would have capacity to serve the patients within Pierce County. Therefore, the department concludes that approval of this project has the potential of fragmentation of dialysis services within the service area, and this sub-criterion is not met.

FHS-Lakewood & South Pierce

For both of its projects, FHS provided the following statements related to this criterion. [source: FHS-Lakewood Application, p24; FHS-South Pierce Application, pp24-25]

*“FHS has organized renal services such that all services are contained in a single service line. This organizational structure integrates inpatient, outpatient, and home services within a single continuum. This continuum is supported by a computer network which provides appropriate patient and clinical data to care providers throughout the system. The program also has well established working relationships with area nursing homes and provides in-service and training opportunities for nursing home staff and residents. Specific arrangements are made on a resident by*

*resident basis. Therefore, the list of nursing homes that FHS works with varies. While we do not maintain formal working agreements with any party, we have long-standing relationships in place with many Pierce County providers. In addition, FHS has informal relationships with area colleges and universities.”*

The department also considered FHS’s history of providing care to residents in Washington State. The department concludes that the applicant has been providing healthcare services, including dialysis services, to the residents of Washington State for several years and has been appropriately participating in relationships with community facilities to provide a variety of medical services. Nothing in the materials reviewed by staff suggests that approval of this project would change these relationships. [source: CN historical files]

Additionally, the department used the most recent utilization data—September 2006--obtained from the Northwest Renal Network to assist in its evaluation of this sub-criterion. According to that data, of the five existing dialysis centers currently operating in FHS’s identified ESRD service area, two—FHS’s Greater Puyallup Dialysis Center and Gig Harbor Dialysis Center—are both operating below the 80% utilization standard required before additional stations may be added. Based on this information, the department must reasonably conclude that the Greater Puyallup and Gig Harbor centers would have capacity to serve the patients within Pierce County. Therefore, the department concludes that approval of either of the two FHS project have the potential of fragmentation of dialysis services within the service area, and this sub-criterion is not met.

- (5) *There is reasonable assurance that the services to be provided through the proposed project will be provided in a manner that ensures safe and adequate care to the public to be served and in accord with applicable federal and state laws, rules, and regulations.*

For all three projects, this sub-criterion is addressed in sub-section (3) above and is considered met.

#### **D. Cost Containment (WAC 246-310-240)**

Based on the source information reviewed, the department determines that both applicants have not met the cost containment criteria in WAC 246-310-240.

- (1) *Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.*

DaVita, Inc.

Within the application, DaVita provided discussion regarding the following two alternatives to this project. [source: DaVita-Tacoma Application, pp29-30]

a) Do nothing or status quo

DaVita states that delays and on-going litigation have caused substantial delays for any operator serving Pierce County patients. Based on DaVita’s numeric methodology, a 29 station need in Pierce County has been demonstrated which increases to 35 station need in year 2010. Since DaVita has already built the facility that would house the dialysis center, not establishing TDC would leave an estimated residual cost of \$1,615,950 and would not address the current shortage of dialysis stations within the county. Based on this rationale, DaVita rejected this option.

b) Establish a 16-station center in Tacoma

DaVita provided the following discussion regarding this option.

*“This approach would return Pierce County to its original position of having approved 16 stations and providing adequate capacity within the Pierce sub-service area while providing an opportunity for expansion in other parts of Pierce County. This project would represent reasonable (but not the best) capital expenditure efficiency and reasonable staffing productivity and adequate short term station capacity only if other Certificate of Need projects could be rapidly implemented which is not a likely scenario.”*

Based on DaVita’s discussion of the two options above, both options were rejected before submitting this project.

FHS-Lakewood and South Pierce

Before submitting its applications for an 8-station facility in Lakewood and an 18-station facility in south Pierce County, FHS considered and rejected the following three alternatives. [source: FHS-Lakewood Application, pp27-28; FHS-South Pierce Application, pp27-28]

a) Do nothing or status quo

FHS rejected this option for both projects based on its application of the numeric methodology for Pierce County. Additionally, related to the south Pierce County project, FHS asserts that if additional stations are located in areas other than the Spanaway area, residents will be “shut out” from improved access through at least the year 2010.

b) Establish an 18-24 dialysis center on the St. Clare Hospital campus

FHS ruled out this option for three reasons: 1) space demands at the hospital are high and sufficient space was not available; 2) construction on a hospital campus is more costly than freestanding due to code requirements and the need to work around an existing hospital with 24/7 operations; and 3) establishing a large facility in Lakewood does not offer a significant improvement in access to patients since DaVita already operates a unit in Lakewood. The 8-station facility is approximately 1.2 miles from the existing DaVita Lakewood facility.

c) Establish a 24-station dialysis center in Spanaway with dedicated training stations

For the Lakewood project, this option was rejected by FHS because of increasing requests from patients and providers for another hospital-based dialysis location. FHS asserts that the more frail and non-ambulatory patients prefer the permanent beds and the immediate access to physicians, pharmacy, radiology, etc that is typically only available through a hospital-based site. For the south Pierce County project, FHS preferred to establish a unit nearer to Spanaway, however, there are no existing sewer lines for that area, and none are proposed. FHS would have to expend the additional dollars to extend the sewer line (\$700,000), which was not considered by FHS to be prudent.

After reviewing the three options summarized above, FHS determined that a smaller unit on the St. Clare Hospital campus (8 stations) and a larger unit in south Pierce County (18 stations) were considered to be the best options.

The department recognizes that all three projects would increase the dialysis station capacity in the county. Additionally, the numeric portion of the need methodology supports the addition of stations to Pierce County. However, as previously concluded in this evaluation, according to the most recent NRN data, of the existing dialysis centers currently operating in

the county, two—FHS’s Greater Puyallup Dialysis Center and Gig Harbor Dialysis Center—are operating below the 80% utilization standard required before additional stations may be added. Therefore, stations are available at existing dialysis facilities to meet the identified need. Based on this information, the department concludes that the county has capacity to serve the patients in both DaVita’s and FHS’s identified service areas. As a result, the department concludes that adding station capacity to Pierce County is not the best available alternative at this time, and this sub-criterion is not met.

(2) In the case of a project involving construction:

(a) The costs, scope, and methods of construction and energy conservation are reasonable; DaVita, Inc.

FHS-Lakewood and South Pierce

As stated in the project description portion of this evaluation, all three projects involve construction. This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concludes that this sub-criterion is not met for all three projects.

(b) The project will not have an unreasonable impact on the costs and charges to the public of providing health services by other persons.

This sub-criterion is also evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concludes that this sub-criterion is not met for all three projects.